(a) applying a coating to the stent, the coating containing a complex of heparin with an aromatic quaternary ammonium ion dispersed in a copolymer of ethylene with vinyl alcohol; and

(b) heat-treating the coating.

59. (Amended) The method of Claim 58, wherein the heat-treating is conducted within a temperature range of about 50°C to about 100°C.

REMARKS

This response, and accompanying request for continued examination, addresses the Final Office Action mailed on March 11, 2002. Claims 37 and 40-59 are pending. The numbered paragraphs below correspond to the Examiner's numbered paragraphs.

1./2. Claim 38 has been canceled. With respect to Claim 44, "the coating" refers to the coating of Claim 37. To clarify the ambiguity, the limitation "the primer coating" has been replaced with "primer" in Claim 41 and throughout the claims.

With respect to Claim 48, the Examiner objected to the use of the trade mark DURAFLO. The Applicants submit that reciting the trade name DURAFLO does not render Claim 48 indefinite. The Manual of Patent Examining Procedure permits such use of trade marks if either of the following two conditions met:

> (A) Their meanings are established by an accompanying definition which is sufficiently precise and definite to be made a part of a claim, or
>
> (B) In this country, their meanings are well-known and satisfactorily defined in the literature. MPEP § 608.01(v).

To make the use of a trade name permissible, it should be "distinguished from common descriptive nouns by capitalization." MPEP § 608.01(v).

The Applicants submit that all of the above-described conditions to make the use of a trade name permissible in the claims have been satisfied. The meaning of the mark DURAFLO has been defined in the original specification with sufficient precision and definiteness.

DURAFLO has been defined as a "commercial heparin derivative," which is available from Baxter International. No exact chemical name or formula of DURAFLO can be provided because it appears, after reasonable diligence by the Applicants, that the holder of the mark has kept its formulation a trade secret. With respect to the requirement of capitalization, the word is capitalized in Claim 48.

Consequently, the Applicants represent that the claims are definite and withdrawal of the 35 U.S.C. §112, second paragraph, rejection with respect to Claims 44 and 48 is requested.

6. Claims 37 and 48 have been rejected under 35 U.S.C. §102(b) as being anticipated by Rowland et al. (U.S. Patent No. 5,356,433). Rowland et al. teach coating stents using a heparin/TDMAC complex (Col. 7, lines 11-31). Rowland et al. fail to teach "**a complex of heparin with an aromatic quaternary ammonium ion dispersed in the copolymer of ethylene with vinyl alcohol**," as recited by Claim 37. TDMAC (tridodecylmethyl ammonium chloride) is not an aromatic, but rather aliphatic quaternary ammonium ion. Accordingly, Claim 37 is patentably allowable over Rowland et al. Claim 48 depends from Claim 37 and is therefore patentably allowable for at least the same reason. Withdrawal of the rejection is respectfully requested.

7. Claims 37 and 49-51 have been rejected under 35 U.S.C. §102(e) as being anticipated by Shah et al. (U.S. Patent No. 6,248,127 B1). Shah et al. teach coating stents using only a heparin/TDMAC complex. Shah et al. fail to disclose "**a complex of heparin with an aromatic quaternary ammonium ion dispersed in the copolymer of ethylene with vinyl alcohol**," as recited by Claims 37 and 49. Accordingly, Claims 37 and 49 are each patentably allowable over Shah et al. Claims 50 and 51 depend from Claim 49 and are patentably allowable for at least the same reason. Withdrawal of the rejection is respectfully requested.

8. Claims 37, 41, 48-51, and 58-59 have been rejected under 35 U.S.C. §102(e) as being anticipated by Ding et al. (U.S. Patent No. 6,316,018 B1). Ding et al. also fail to teach "**a**

complex of heparin with an aromatic quaternary ammonium ion dispersed in the copolymer of ethylene with vinyl alcohol," as recited in Claims 37, 49, and 58.

Accordingly, Claims 37, 49 and, 58 are patentably allowable over Ding et al. Claims 41 and 48 depend from Claim 37 and are patentably allowable for at least the same reason. Claims 50 and 51 depend from Claim 49 and are patentably allowable for at least the same reason. Claim 59 depends from Claim 58 and is patentably allowable for at least the same reason. Withdrawal of the rejection of is respectfully requested.

14. Claims 37, 38, 41, 44, 48-51, and 58-59 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Zhong (U.S. Patent No. 6,197,051 B1) in view of Shah et al. As indicated above, Shah et al. fail to teach "**a complex of heparin with an aromatic quaternary ammonium ion dispersed in the copolymer of ethylene with vinyl alcohol,**" as recited by Claims 37, 49 and 58. Zhong fails to cure these deficiencies. Zhong teaches to use only heparin or heparin sulfate (Col. 7, lines 27-28). Nowhere in Zhong is "a complex of heparin with an aromatic quaternary ammonium ion dispersed in the copolymer of ethylene with vinyl alcohol" suggested or implied. Accordingly, the Shah et al. and Zhong references, alone or in combination, fail to teach every element of Claims 37, 49 and 58.

Therefore, Claims 37, 49 and 58 are patentably allowable over Zhong in view of Shah et al. Claim 38 has been canceled. Claims 41, 44 and 48 depend from Claim 37 and are patentably allowable for at least the same reason. Claims 50-51 depend from Claim 49 and are patentably allowable for at least the same reason. Claim 59 depends from Claim 58 and is patentably allowable for at least the same reason. Withdrawal of the rejection is respectfully requested.

15. Claims 40, 43, 52-57 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Zhong in view of Shah et al. and further in view of Hostettler et al. (U.S. Patent No. 5,662,960). As indicated above, neither Shah et al. nor Zhong, alone or in combination, discloses "**a complex of heparin with an aromatic quaternary ammonium ion**

dispersed in the copolymer of ethylene with vinyl alcohol," as recited by Claims 37, 49 and 53. Hostettler et al. fails to cure these deficiencies. Nowhere in Hostettler et al. is the use of "a complex of heparin with an aromatic quaternary ammonium ion dispersed in the copolymer of ethylene with vinyl alcohol," is suggested or implied. Accordingly, the Shah et al., Zhong and Hostettler et al. references, alone or in combination, fail to teach every element of Claims 37, 49 and 53.

Therefore, Claims 37, 49 and 53 are patentably allowable over Zhong in view of Shah et al. and further in view of Hostettler et al. Claims 40 and 43 depend from Claim 37 and are patentably allowable for at least the same reason. Claim 52 depends from Claim 49 and is patentably allowable for at least the same reason. Claims 54-57 depend from Claim 53 and are patentably allowable for at least the same reason. Withdrawal of the rejection is respectfully requested.

16. Claims 37, 38, 40-43, 45-53 and 57 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hostettler et al. (U.S. Patent No. 6,030,656) ("Hostettler '656") in view of Shah et al. As indicated above, Claims 37, 49 and 53 are patentably allowable over Shah et al. Hostettler '656 fails to cure these deficiencies. Hostettler '656 only teaches to use pure heparin for reacting "with the spacer component-treated modified polymeric surface" (Col. 4, lines 52-53). Nowhere in Hostettler '656 is the use of "a complex of heparin with an aromatic quaternary ammonium ion" suggested or implied. Moreover, Hostettler '656 implicitly teaches away from using "a complex of heparin with an aromatic quaternary ammonium ion" because the reactivity of such complex will be too low for reacting "with the spacer component-treated modified polymeric surface." Accordingly, the Shah et al. and Hostettler '656 references, alone or in combination, fail to teach every element of Claims 37, 49 and 53.

Therefore, Claims 37, 49, and 53 are patentably allowable over Hostettler '656 in view of Shah et al. Claim 38 has been canceled. Claims 40-43, and 45-48 depend from Claim 37 and

are patentably allowable for at least the same reason. Claims 50-52 depend from Claim 49 and are patentably allowable for at least the same reason. Claim 57 depends from Claim 53 and is patentably allowable for at least the same reason. Withdrawal of the rejection is respectfully requested.

17. Claims 37-39 have been rejected under 35 U.S.C. §103(a) as being unpatentable over a combination of Onishi et al. (U.S. Patent No. 5,670,558) and Shah et al. As indicated above, Shah et al. fail to disclose "a complex of heparin with an aromatic quaternary ammonium ion" as recited by Claim 37. Onishi et al. fail to cure this deficiency. Onishi et al. only teach applying a polymer on the medical device, then immerse the polymer-coated device "in a solution of a low-molecular weight heparin" (Col. 13, lines 51-52). Accordingly, the Onishi et al. and Shah et al. references, alone or in combination, fail to teach every element of Claim 37.

Therefore, Claim 37 is patentably allowable over the combination of Onishi et al. and Shah et al. Claims 38 and 39 have been canceled. Withdrawal of the rejection is respectfully requested.

CONCLUSION

Claims 37 and 40-59 are pending in this application. Examination and allowance of the claims is respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned at (415) 954-0349.

Date: August 2, 2002

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as express mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231, on August 2, 2002.

Date: August 2, 2002 By: Linda Fare
Name of person signing certification

Version With Markings To Show Changes Made

In the Claims:

Please amend the claims as indicated below.

37. (Amended) A method of coating a stent, the method comprising applying a coating to the [said] stent, the [said] coating comprising:

(a) a copolymer of ethylene with vinyl alcohol;

(b) a complex of heparin with an aromatic quaternary ammonium ion dispersed in the copolymer of ethylene with vinyl alcohol [a heparin compound having a hydrophobic counter ion]; and

(c) a therapeutic substance dispersed with the complex of heparin.

Please cancel Claims 38 and 39.

40. (Amended) The method of Claim 37, further comprising roughening at least a region of the surface of the [said] stent prior to applying the [said] coating.

41. (Amended) The method of Claim 37, further comprising applying a primer [coating] on the surface of the [said] stent prior to applying the [said] coating.

42. (Amended) The method of Claim 41, wherein the [said] primer [coating] is made of a material selected from a group consisting of ethylene vinyl alcohol copolymer, polycystine, polylysine, and reactive silanes, the [said] reactive silanes comprising trimethoxysilane.

43. (Amended) The method of Claim 41, further comprising roughening at least a region of the surface of the [said] stent prior to applying the [said] primer [coating].

44. (Amended) The method of Claim [43] 41, further comprising heat-treating the [of said] coating.

45. (Amended) The method of Claim 41, wherein the [said] primer [coating] contains at least one chlorosilane compound.

46. (Amended) The method of Claim 45, wherein the [said] chlorosilane compound has a functional head.

47. (Amended) The method of Claim 46, wherein the [said] functional head comprises an unsaturated group, an amino group, or a carboxyl group.

48. (Amended) The method of Claim 37, wherein [said heparin compound] the complex of heparin is DURAFLO.

49. (Amended) A method of coating an implantable medical device, the method comprising coating the [said] device with a composition, the composition including:

(a) a copolymer of ethylene with vinyl alcohol;

(b) a complex of heparin with an aromatic quaternary ammonium ion [a heparin compound having a hydrophobic counter ion] dispersed in the copolymer of ethylene with vinyl alcohol; and

(c) at least one adhesion enhancer.

50. (Amended) The method of Claim 49, wherein the [said] adhesion enhancer is selected from a group consisting of poly(ethylene glycol), poly(ethylene oxide), poly(vinylpyrrolidone), poly(vinyl alcohol), poly(caprolactone), poly(glycolic acid), [poly(ethylene-co-vinyl alcohol),] hyaluronic acid, polyurethanes, copolymers of caprolactone and glycolic acid, copolymers of caprolactone and ethylene glycol, segmented polyurethanes, and mixtures thereof.

51. (Amended) The method of Claim 49, wherein the [said] coating is performed by dip coating or spraying.

52. (Amended) The method of Claim 49, further comprising roughening at least a region of the surface of the [said] device prior to coating.

53. (Amended) A method of coating a stent, the method comprising:

(a) roughening at least a region of the surface of the [said] stent; and

(b) applying a coating to the stent, the coating containing a complex of heparin with an aromatic quaternary ammonium ion [heparin compound having a hydrophobic counter ion to said stent] dispersed in a copolymer of ethylene with vinyl alcohol.

54. (Amended) The method of Claim 53, further comprising heat-treating the [of said] coating.

55. (Amended) The method of Claim 54, wherein the [said] heat-treating is conducted within a temperature range of about 50°C to about 100°C.

56. (Amended) The method of Claim 53, wherein the [said] roughening is performed by argon plasma etching.

57. (Amended) The method of Claim 53, further comprising applying a primer [coating] on the surface of the [said] stent prior to applying the [said] coating.

58. (Amended) A method of coating a stent, the method comprising:

(a) applying a coating to the stent, the coating containing a complex of heparin with an aromatic quaternary ammonium ion [heparin compound having a hydrophobic counter ion to said stent] dispersed in a copolymer of ethylene with vinyl alcohol; and

(b) heat-treating the [of said] coating.

59. (Amended) The method of Claim 58, wherein the [said] heat-treating is conducted within a temperature range of about 50°C to about 100°C.